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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/063,778 04/22/98 ARIYASU

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001444 HM12/1010
BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON DC 20001-5303

EXAMINER

KAUFMAN, C

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

10/10/00

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/063,778

Applicant(s)

ARIYASU ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 is/are allowed.
- 6) ☒ Claim(s) 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

The amendment filed 7/13/00 has been entered as requested by the CPA.

Continued Prosecution Application

5 The request filed on July 14, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/063,778 is acceptable and a CPA has been established. An action on the CPA follows.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

15 Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

 Claim 24 is indefinite because it recites Gly-20 in the second to last line, but there is no glycine at that position. It appears from previous now cancelled claim 23 that Applicants might have intended Gly-29.

Claim Rejections - 35 USC § 112, First Paragraph

20 Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

25 Claim 24 is a product-by-process claim. Two aspects of it represent new matter. The first is the use of a sense primer encoding a part of SEQ ID NO:3 in the region of amino acid -22 to -1 and an antisense primer from the encoding region of amino acids 177-374. The second is conservation of amino acid residues corresponding to Glu-155 and one or more of Ala-14, Gly-20, and Ala-46 of the amino acid sequence of SEQ ID NO:1.

In the first instance, while specific primers from within the recited region are disclosed in the specification (SEQ ID NO: 13 and 14), and while the regions represent the encoding signal sequence and C-terminal portion of the protein, there is no generic disclosure that primers can be chosen from those regions for amplification of a human Desert hedgehog (hDhh)-encoding nucleic acid. One example of primers in the specification does not provide basis for the breadth of primer selection appearing in claim 24.

In the second instance, while the sequence of hDhh is disclosed and the sequence of mouse Dhh was known in the prior art, these two sequences do not provide a basis for particular amino acids which are conserved in hDhh proteins. Applicants point to basis for this limitation (p. 6 of response filed 1/4/00) in the paragraph bridging pages 23-24 of the specification, which describes the mouse Dhh sequence of SEQ ID NO:7, and in the exhibit showing amino acid sequence alignment of mouse and human Dhh and hShh. While it disclosed that hDhh protein may differ from Dhh sequences of other species, this is a general concept. There is no disclosure of a protein which differs specifically as described in claim 24 (this holds even if Gly-29 was intended instead of Gly-20). The specification does not disclose specific amino acids which are conserved in human Dhh sequences. Claims may be amended to carve around prior art or distinguish the claimed subject matter, however, there must be adequate written description in the specification as filed for this. It does not appear that there is sufficient basis in the specification for the limitation requiring particular amino acids.

Conclusion

Claims 1-4 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Art Unit: 1646

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

October 6, 2000